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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,974	11/08/2000	Philip A. Beachy	JHUC-P03-010	3945

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/22/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,974

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8, 11-17, 20, 22, 24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-8, 11-17, 20, 22, 24 and 26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 3-8, 11-17, 20, 22, 24 and 26 are pending in the present application. Claim 4 stands withdrawn from further consideration as being drawn to a nonelected invention. Claims 3, 5-8, 11-17, 20, 22, 24 and 26 are examined to the extent they read on compounds having the basic chemical structure of cyclopamine or jervine.

Double Patenting

3. The provisional rejection of claim 25 under the judicially created doctrine of obviousness-type double patenting over claims 1, 15-17, 20, 21, 27, 28 and 36 of copending Application No. 09/708,964 is made moot by the cancellation of the instant claim.

- w 4. The provisional rejection of claims 3, 5-8, 11-17, 20, 22, 24 and 26 under the judicially created doctrine of obviousness-type double patenting over claims 1, 15-17, 20, 21, 27, 28 and 36 of copending Application No. 09/708,964 is maintained.

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Applicant's statement that the claims will be amended and/or a terminal disclaimer filed upon indication of allowable subject matter is noted.

Claim Rejections - 35 USC § 112

5. The rejection of claims 5, 6, 8 and 11 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 102

6. The rejection of claim ~~25~~ under 35 USC 102(b) over Gerashchenko et al. is made moot by the cancellation of the instant claim.

7. The rejection of claims ~~24~~ and ~~26~~ under 35 USC 102(b) over Gerashchenko et al. is maintained.

Applicant argues the reference (a) teaches an aqueous preparation that was injected and (b) does not teach treating unwanted hair growth or inhibiting spermatogenesis and, thus, does not anticipate the instant claims. Applicant's argument was considered but not persuasive for the following reasons.

Claim 24 is directed to a pharmaceutical preparation formulated for topical application. The use of aqueous solutions as topical preparations is known in the pharmaceutical art (see for example, WO 96/35412, Abstract; EP 0495684, Abstract; US 6,495,532, col. 35, lines 9-10). Thus, the claimed composition in aqueous form is encompassed by the instant claim.

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Claim 26 is drawn to process for manufacturing a medicament in a pharmaceutically acceptable excipients. The intended ^{use} of the medicament does not lend patentability to the process and, thus, the process utilized by the cited reference is encompassed by the instant claim.

For these reasons and those given in Paper NO. 20, the rejection of claims 24 and 26 under 35 USC 102(b) over Gerashchenko et al. is maintained.

8. The rejection of claim ~~25~~ under 35 USC 102(b) over Omnell et al. is made moot by the cancellation of the instant claim.

9. The rejection of claims ~~24~~ and ~~26~~ under 35 USC 102(b) over Omnell et al. is maintained.

Applicant's argument and the examiner's response are as discussed above in #7.

For these reasons and those given in Paper NO. 20, the rejection of claims 24 and 26 under 35 USC 102(b) over Omnell et al. is maintained.

Claim Rejections - 35 USC § 103

10. The rejection of claim 25 under 35 USC 103(a) over Gerashchenko et al. or Omnell et al. is made moot by the cancellation of the instant claim.

Other Matters

11. It is noted that claims 3, 5-8, 11-17, 20 and 22 drawn to inhibition of unwanted hair growth or spermatogenesis utilizing compounds having the basic chemical skeleton as cycloamine or jervine would be allowable upon filing of an amendment and a terminal disclaimer if needed.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
May 20, 2003